ONTARIO MINISTRY OF ENVIRONMENT
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A BRIEF ON 2,4,5-T AND 2,4,5-TP

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Ontario

Ministry
of the
Environment

The Honourable
Harry C. Parrott, D.D.S.,
Minister

Graham W. S. Scott,
Deputy Minister

A
BRIEF
ON
2,4,5-T AND 2,4,5-TP

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HISTORY

Phenoxy herbicides have been used since the early 1940's to control unwanted weeds and brush. 2,4,5-T and 2,4,5-TP are phenoxy herbicides first used in 1948. The use of this type of herbicide has been and still is in extensive use around the world. Use experience has shown very few if any problems or controversy prior to 1968.

The first research to identify or question birth effects from 2,4,5-T came in 1969 and was done by Dr. Dianne Courtney of the National Cancer Institute's Bionetics Research Laboratory. Dr. Courtney reported birth defects such as cleft palate and abnormal kidneys in mice and rats treated with large quantities of 2,4,5-T. The cause of these findings was controversial from several points. The 2,4,5-T used in the research was contaminated with 2,3,7,8 tetrachlorodibenzo-p-dioxin (TCDD). This contaminant is extremely toxic and was felt by some to be the causal agent of the defects reported by Courtney in her research.

The issue was further complicated by the extremely heavy use of 2,4,5-T (Agent Orange) in the controversial war in Vietnam. Allegations were then presented that birth defects in Vietnamese women were caused by 2,4,5-T spraying of the jungle.

In December 1969 the Ontario Pesticides Advisory Board was requested by the Minister of Health to report on 2,4,5-T and other phenoxy herbicides.(1). This report, submitted in July of 1970, concluded that no hazard existed in Ontario as a result of the use of 2,4,5-T and that no further regulatory action was necessary.

In June of 1970, Agriculture Canada removed the home and recreational uses of 2,4,5-T from Canadian pesticide product labels as a safeguard for exposure of pregnant women. The other registered uses of 2,4,5-T were not affected.

Home uses of 2,4,5-T and recreational uses were removed for sale in the U.S. by Department of Agriculture also in 1970.

The Vietnam birth defect allegations were the cause of several investigations by various U.S. agencies. In May of 1971, the Advisory Committee on 2,4,5-T submitted a report to the United States Environmental Protection Agency which concluded that its medical investigations found no evidence of adverse effects on human reproduction in 3 separate high-use investigations including Vietnam (2). The effects of herbicide usage in Vietnam and its relevance to use in United States was investigated and reported on by the Council for Agricultural Science and Technology (CAST). These reports concluded that there was no correlation between 2,4,5-T spraying and birth defects or stated that no conclusions could be drawn because of insufficient data (3).

In 1977 the New Zealand Department of Health studied the implications of the use of 2,4,5-T in that country. In short, the conclusion of this report was that 2,4,5-T is not responsible for human birth defects (4).

On April 1978, the E.P.A. published a Rebuttable Presumption Against Registration (RPAR) and Continued Registration of Pesticides Products containing 2,4,5-T(5). This official action by E.P.A. identifies concerns

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with the continued use of 2,4,5-T and formally requires the manufacturers to provide evidence to satisfy the concerns. This involves the gathering of all pertinent scientific data by all parties and a formal review of the same. The RPAR process was expected to take approximately eighteen months to two years to finalize the status of 2,4,5-T use in the U.S.

In August of 1978, a further report of the U.S. Council for Agricultural Science and Technology (CAST) was published which reviewed the benefits and hazards associated with the use of 2,4,5-T and 2,4,5-TP. One of the conclusions of this report is that the use of 2,4,5-T and 2,4,5-TP with their contaminant TCDD do not endanger human health, animals or the environment (6). Also in 1978 the effects on environmental quality of phenoxy herbicides was assessed and documented by the National Research Council. The Report recommends several areas of research which could be investigated but does not identify any urgent need for these studies. The report does not suggest any restrictions of the use of these herbicides.

Australia also uses large quantities of phenoxy herbicides and is equally concerned if a causal relationship exists between their use and human health, specifically birth defects. As a result of a 1978 review and study, it has been concluded that there is no evidence that birth defects were caused by 2,4-D or 2,4,5-T and that no new legislative controls are needed (8).

The Ministry of Environment's Pesticides Advisory Committee in February 1979 reviewed and reported upon the use of all phenoxy herbicides in Ontario with particular emphasis on use by Ontario Government Agencies. The conclusion of this report is that the use of phenoxy herbicides and picloram are justified and safe. They do not suggest any additional legislative control over their use(9).

Each of the previously mentioned reports documents many pieces of scientific literature. There are also huge volumes of other information concerning 2,4,5-T and 2,4,5-TP. The reports mentioned are summaries and official positions of organizations or advisers to Governments and present no suggestion of further restriction on prohibition except for the EPA's RPAR document.

CANADIAN GOVERNMENT CONTROL

Pesticides are regulated across Canada under the Pest Control Products Act which is administered by Agriculture Canada. The conditions under which the products are to be sold and used are set forth in a registered use pattern for each product. Each pesticide product is identifiable by a code in the registered products list and a P.C.P. number specific to the products and its trade name.

The application for registration of a product is submitted with sufficient scientific data to allow evaluation of the product in respect to efficacy and safety by Agriculture Canada, Fisheries and Environment Canada, and National Health and Welfare Canada.

The registration procedure is very complex and takes into consideration the data on efficacy, residues, tolerance levels and environmental impact reflecting differences in soil, climate, use areas and cultural practices. The hazards associated with the manufacturer, user, non-users and non-target areas or organisms, notes on toxicity, handling and disposal are reviewed. The health aspects include exposure routes, sub-clinical effects, residues and tolerances, for food. Also tissue storage, metabolism, reproduction, teratogenicity, mutagenicity and carcinogenicity are considered.

The goal of this process is to establish an acceptable use pattern for the product and set forth the conditions under which the products may be sold and used. Registered products are subject to re-evaluation on the basis of experience, new data or alternative product availability.

Agriculture Canada to this date has reviewed the use of 2,4,5-T and 2,4,5-TP and has taken two actions to further control these two herbicides. As previously mentioned in June 1970, home and recreational uses were cancelled from the registered uses as a precaution. Agriculture Canada limited the concentrations of TCDD in products to less than 0.5 ppm for 1974 and further reduced this to 0.1 ppm for 1975. Agriculture Canada and its federal advisors in other departments are continually reviewing new data as they become available and have not suggested any further restrictions in use across Canada.

TCDD (2,3,7,8 tetrachlorodibenzo-p-dioxin)

TCDD is a contaminant which is found in products of 2,4,5-T and 2,4,5-TP but is not present in other phenoxy herbicides (eg. 2,4-D, mecoprop, dichlorprop); Most of the reports previously mentioned identify TCDD as the toxic agent which may cause laboratory animal birth defects.

The contamination of 2,4,5-T with TCDD was highest in the mid 1970's when the military use of this herbicide was highest. The most contaminated batches are reported to have contained up to 300 ppm of TCDD. Normally used domestic supplies used in the late 1960's and early 1970's probably contained 25-30 ppm of TCDD. Because of the concern over the presence of TCDD which was identified only in the early 1970's, the manufacturers have refined the manufacture of 2,4,5-T so that levels are now well below the legal requirement of 0.1 ppm of TCDD in products. The chemical analysis of TCDD has been greatly improved and today as little as 0.1 ppb can be detected.

Animal fats and foods have been sampled by Canadian Health Agencies and no residues have been found of TCDD. Research on residues and the possible impact of TCDD are ongoing around the world. The Dow Chemical Company has conducted extensive research studies that indicate that TCDD and other dioxins may be produced by combustion and have therefore been in our environment always. The Dow research may have value and does provide new analytical methods which can detect TCDD in quantities of as little as 10 ppt. The ability to detect these miniscule quantities may help to provide new data not previously available.

CURRENT SITUATION

On March 1, 1979 the Assistant Administrator for E.P.A. announced an Emergency Suspension Order relating to uses of 2,4,5-T and 2,4,5-TP for forestry, rights-of-way and pastures uses. The uses on rice and rangeland were not included in this order. The affect of this order was to stop all sale and use of these two herbicides immediately for the above uses across the United States. The decision documents were provided one month later by E.P.A. (10) & (11). This type of emergency action has never been taken by E.P.A. in the past. This action stops the RPAR review process for the suspended uses but it will be continued for rice and rangeland uses.

The prime reason for E.P.A.'s action was an internal report of February 20, 1979 on spontaneous abortions and 2,4,5-T forest spraying in Alsea, Oregon (12). A copy of this report was provided by Agriculture Canada on March 14, 1979. This report was forwarded to the Ontario Pesticides Advisory Committee for an assessment. The E.P.A. report identifies a correlation in time between spontaneous abortions and earlier applied 2,4,5-T sprays. It uses two different areas of Oregon as checks; an urban area and an area remote from 2,4,5-T spraying.

E.P.A. investigators interviewed some doctors and reviewed hospital records to obtain data. They then related this data to use figures. By the application of statistical models a correlation is presented.

On March 6, 1979, Dow Chemical Company sued E.P.A. on the basis that the decision was arbitrarily based on an E.P.A. document and not considering all the available scientific data. Since March 6, 14 other organizations have joined as parties to the Dow suit. This case was heard April 4,5 and 6 by a Michigan State judge but he has not handed down his decision as yet. On March 8, 1979, Dow Chemicals of Canada provided to the Pesticides Control Section, MOE, copies of an earlier, non-conclusive Oregon study and an evaluation of E.P.A.'s recent study which challenges the methods of the study, the conclusions of the study and E.P.A.'s subsequent action (13).

On March 20, 1979 In Ottawa, E.P.A. staff provided a discussion of E.P.A.'s decision. The staff present were unable to answer questions as to essential data comparisons between the Alsea area and the two control areas. They did however, state that E.P.A.'s contention is that a statistical correlation exists between 2,4,5-T spraying and spontaneous abortions and that they do not claim to have shown a causal relationship.

On March 27, 1979 in Washington, Mr. Ed Johnson, Assistant Deputy Administrator of E.P.A. presented E.P.A.'s position and rationale concerning 2,4,5-T and 2,4,5-TP. Mr. Johnson and staff were not able to provide basic data or comparison data for the control areas. This presentation was made to the American Association of Pesticide Control Officials' (AAPCO) meeting. State officials were unable to have questions answered as to the emergency nature of the restrictions. Mr. Johnson said that E.P.A. has no plans to revisit the Alsea area or to conduct epidemiological studies elsewhere. One point brought out by E.P.A. was the difficulty in utilizing hospital records due to patient confidentiality. The Association then passed a resolution which was to be sent to the Administrator of E.P.A. asking that the emergency provision of the March 1 order be dropped and that the E.P.A. study be considered along with all the other data being prepared for the RPAR process. They also point out in the resolution that the study does not show a cause and effect relationship. This resolution was passed unanimously with 38 states represented.

On March 28, 1979 at the same AAPCO meeting the National Forest Products Association presented an assessment of the E.P.A. study by Dr. Nathan Mantel, a world renowned biostatistician from George Washington University (14). Dr. Mantel's final remark is that no weight can be given to the conclusion of E.P.A.'s Oregon report due to the incorrect use of data and the lack of sufficient data.

The same association presented a study conducted for them by Dr. T. L. Lavy, University of Arkansas on the exposure of flagmen and mixers to 2,4,5-T during an actual aerial forestry operation. These two groups were chosen because they would have the greatest potential exposure during an actual application. This study used the most up-to-date exposure measurement techniques and appears to be extremely well done and to be one of the first examples of this techniques to assess risk. The safety factors when exposure is compared to the most sensitive no-effect level in test animals was 700 times for mixers and 17,500 times for flagmen. This study indicates a very acceptable safety margin for workers involved in the use of 2,4,5-T.

On April 2, 1979 The Ontario Pesticides Advisory Committee presented its assessment of E.P.A.'s Oregon Study. The Committee is of the opinion that the study cannot be used as a scientific basis for recommending further legislative restrictions or changes in Provincial recommendations. The Committee also feels that the recent amendments to the Ontario Pesticides Act give Ontario excellent control and maximum flexibility to make changes.

CONCLUSION

All of the foregoing supports the position that the Ontario Ministry of the Environment should continue to allow the use of 2,4,5-T and 2,4,5-TP (Silvex) under the recently adopted permit system. The use of the permit system will ensure that the Ministry has an up-to-date record of the use of these two herbicides and an ability to selectively curtail the use of them should new information come to light.

The following use permit policy will ensure the safe and orderly application of these controversial herbicides in Ontario.

USE PERMIT POLICY

The Pesticides Control Section, Ministry of the Environment, will ensure that each permit will be issued only when the following criteria are met:

1. A completed permit application has been submitted for the use of 2,4,5-T and 2,4,5-TP (Silvex).
2. Each piece of application equipment will be operated by an appropriately qualified applicator or a licenced exterminator.
3. The rate of application, total gallonage of spray, pest vegetation and all other details are consistent with registered product labels.
4. Each applicant will be required to submit a plan of operation which indicates the need for the use of the herbicide along with a statement of safe practices near residential areas and surface water as well as other pertinent details. Detailed maps showing areas to be treated will also be required.
5. Following the spray season, each applicant will be required to report on the exact amount of herbicide used, within the limits of the permitted amounts, and the pattern of use.

ADDITIONAL ACTION

The Ontario Ministry of the Environment through its Pesticides Control Section and the Ontario Pesticides Advisory Committee will continue to gather and assess developing information concerning 2,4,5-T, 2,4,5-TP and alternate herbicides.

Recognizing the roles of both the Federal and Provincial governments, it is recommended that Agriculture Canada undertake an assessment of the need for epidemiological studies relating to the Canadian use of 2,4,5-T and 2,4,5-TP.

The Ontario Ministry of the Environment will offer to assist Agriculture Canada with any investigations it initiates.

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2) Report to the Administrator E.P.A. Advisory Committee on 2,4,5-T, May, 1971.

3) Effects of Herbicides in Vietnam and their Relation to Herbicide Use in the United States. Council for Agricultural Science and Technology, August 7, 1975.

4) 2,4,5-T and Human Birth Defects. Department of Health, New Zealand, June, 1977.

5) Pesticide Programs - Rebuttable Presumption Against Registration and Continued Registration of Pesticide Products Containing 2,4,5-T. Federal Register, April 21, 1978.

6) The Phenoxy Herbicides. Council for Agricultural Science and Technology, August, 1978.

7) Phenoxy Herbicides - Their Effects on Environmental Quality, National Research Council of Canada, Report No. 16075, July, 1978.

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10) Decision and Emergency Order Suspending Registrations for the Forest, Rights-of-way and Pasture Uses of 2,4,5-Trichlorophenoxyacetic Acid (2,4,5-T). U.S. E.P.A., Office of Pesticide Programs. February 28, 1979.

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13) Dow Chemical Evaluation of E.P.A. Epidemiology Study, Alsea, Oregon plus four (4) other related papers. March 5, 1979.

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16) Report of Assessment of a Field Investigation of Six-year Spontaneous Abortion rates in Three Oregon Areas in Relation to Forest 2,4,5-T Spray Practices. Ontario Pesticides Advisory Committee, April, 1979.

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